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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,003

07/16/2003

Li-Te Chin

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1673

26181

7590

07/27/2006

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EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,003

Applicant(s)

CHIN, LI-TE

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 23-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 25-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is in response to the After-Non-final amendment filed on 08 May 2006. Claims 1-14 and 23-41 are pending, of which claims 1-14, 15-22, and 25-35 are withdrawn from consideration and claims 23, 24, and 36-41 are under final rejection.

Response to Arguments

Claim Rejections - 35 USC § 112, 1st ¶, written description

The rejection of claims 23, 24, and 36-41 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is maintained in part for claims 23, 24, and 39-41**. Applicant's argument has been fully considered but found only partially persuasive.

Applicant argues that the structure of antibodies is well known in the art, and it is not necessary to describe the structure of the antibodies in the specification or claims as long as the antigen is known. Applicant alleges that Example 16 (page 59-60) of the Written Description Training Materials supports this point.

Applicant's argument is not applicable to the rejected claims, 23, 24, and 39-41, which do not define a known antigen –the target of claimed method, the at least two HIV strains, is not a known antigen because a virus is too big for an antibody to “recognize.” Therefore, claims 23, 24, and 39-41 encompass a broad genus of undefined antibodies and present a scope of invention that is nonanalogous to the disclosure in Example 16 of the Written Description Training Materials. Therefore, the specification does not

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convey possession of the genus of fully human antibodies or antigen-binding fragments in claims 23, 24, and 39-41.

Claim Rejections - 35 USC § 112, 1st ¶, enablement

The rejection of claims 1-3, 6-14, 44-48, 53-62, 64, and 65 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement is **maintained**. Applicant's argument has been fully considered but found unpersuasive.

Applicant alleges that the two references cited in the prior Office Action, Wei *et al.* (2003) and Trkola *et al.* (2005), describe effective treatment of amelioration of HIV infection using antibodies. Finally, Applicant alleges that the claimed antibody likely binds an important epitope that does not vary.

Applicant's opinion seems to lead to a different interpretation than the teachings of the references. Wei *et al.* reported a delay of the course of HIV infection when the antibody neutralization-resistant viruses expanded. Applicant's out-of-context interpretation of this result as reduced symptoms of HIV infection, relying on a sentence that states a temporary but eventually failed effect of the antibodies, is not convincing evidence to enable the instant application. Applicant found a similar sentence in Trkola *et al.*, ignoring the context of the article stressing the fact that the HIV viral load always bounce back after the treatment with antibodies. Furthermore, Applicant's assertion about the binding specificity of the claimed antibody does not address the non-enabled issue of how to use the claimed method for preventing, treating or ameliorating an HIV infection.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Louise Humphrey, Ph.D.
12 July 2006



JEFFREY S. PARKIN, PH.D.
PRIMARY EXAMINER